DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 25, 2015

HTL-Strefa S.A.
Ms. Aleksandra Prazmowska-Wilanowska
QA/RA/ Director
Adamówek 7
95-035 Ozorków
Poland

Re: K143437
Trade/Device Name: Droplet® Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 21, 2015
Received: May 26, 2015

Dear Ms. Prazmowska-Wilanowska:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143437

Device Name
Droplet® Pen Needles

Indications for Use *(Describe)*
The Droplet® Pen Needles are intended for use with pen injector device for the subcutaneous injection of insulin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K143437

As required by the Safe Medical Devices Act of 1990 and in accordance with 21 CFR §807.92(a).

[807.92 (a)(1,2)]

Date Summary Prepared:	June 11, 2015
Submitted By:	HTL-STREFA S.A. Adamówek 7, 95-035 Ozorków POLAND Phone: +48 42 270 00 10 Fax: +48 42 270 00 20
Contact Person:	Aleksandra Prazmowska-Wilanowska QA/RA Director ola.prazmowska-wilanowska@htl-strefa.pl
Trade Name: **Models:**	Droplet® Pen Needles 4mm x 32G, 5mm x 32G, 6mm x 32G, 8mm x 32G, 5mm x 31G, 6mm x 31G, 8mm x 31G, 10mm x 29G, 12mm x 29G
Common Name:	Insulin Pen Needle
Classification name:	Hypodermic Single Lumen Needle
Device Classification:	Class II, 21 CFR § 880.5570 Product Code: FMI
Review Panel:	80 General Hospital

Predicate Devices: [807.92(a)(3)]

The legally marketed devices to which substantial equivalence is claimed are:

Manufacturer	Trade Name	510(k) Number
Becton Dickson & Co.	BD Ultra-Fine	K031200
Becton Dickson & Co.	BD Ultra-Fine	K100005

Reference devices:

Manufacturer	Trade Name	510(k) Number
Novo Nordisk Inc.	Novofine® Plus	K133738
Disetronic Medical Systems	Penfine® Insulin Injection Pen Needle	K013782

Description of Device: [807.92(a)(4)]

The Droplet® Pen Needles are sterile, single use needles designed to be used with commercially available pen-injectors for the subcutaneous injection of insulin. Pen needles are used by consumers, caregivers and healthcare professionals. The pen needle assembly consists of a double-ended cannula that is assembled into an injection molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen injector device. This allows the cartridge end of the cannula to penetrate through the rubber septum of the cartridge. The patient end and the cartridge end of the cannula are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration. There is an inner needle shield assembled over the patient end of the cannula to protect the needle point from damage and accidental needle sticks. There is also an outer protective container. Each pen needle assembly is protected with a peel away seal to provide a sterility barrier. To use a pen needle, the user needs to remove the seal, remove the outer protective cap and attach it to the pen injector. Then the user removes the inner protective cap to expose the needle and make an injection. Following the injection the user inserts the used pen needle into the outer cap to remove the pen needle from the pen injector and dispose of it immediately. The pen needle is individually packaged and sterilized with Gamma radiation. It is intended for single use only. Droplet® Pen Needles are available in the following lengths and gauges: 4 mm x 32G, 5 mm x 32G, 6 mm x 32G, 8 mm x 32G, 5 mm x 31G, 6 mm x 31G, 8 mm x 31G, 10 mm x 29G, 12 mm x 29G.

Indications for Use: [807.92(a)(5)]

The Droplet® Pen Needles are intended for use with pen injector device for the subcutaneous injection of insulin.

Technological Characteristics: [807.92(a)(6)]

A comparison of characteristics of Droplet pen needles and the predicate devices is shown in the table below:

Device Name	**Subject Device**	**Predicate Device #1**	**Predicate Device #2**
Manufacturer	HTL STREFA S.A.	Becton Dickinson	Becton Dickinson
510(k) Number	Pending	K031200	K100005

Intended use		intended for use with pen injector device for the subcutaneous injection of insulin	intended for use with pen injector device for the subcutaneous injection of insulin	intended for use with pen injector device for the subcutaneous injection of drugs, including insulin and exenatide
Operation principle		Manual	Manual	Manual
Design		Needle assembly – cannula, needle hub, inner protective cap, outer protective cap, seal	Needle assembly – cannula, needle hub, inner protective cap, outer protective cap, seal	Needle assembly – cannula, needle hub, inner protective cap, outer protective cap, seal
Product Code		FMI	FMI	FMI
Length		4mm, 5mm, 6mm, 8mm,10mm, 12mm	5mm, 8mm, 12.7mm	4mm
Materials	*Needle tube*	AISI 304 Grade Stainless Steel	AISI 304 Grade Stainless Steel	AISI 304 Grade Stainless Steel
	Hub	Polypropylene	Polypropylene	Polypropylene
	Primary Container and Needle Shield	Polypropylene	Polypropylene	Polypropylene
Biocompatibility		Conforms to ISO10993-1	Conforms to ISO10993-1	Conforms to ISO10993-1
Sterilization		Gamma radiation (validated in accordance with ISO 11137-1 to achieve SAL 10-6)	Gamma radiation	Gamma radiation

Size characteristics of the reference devices:

Manufacturer	Trade Name	Size
Novo Nordisk Inc.	Novofine® Plus	**32G x 6mm**
Disetronic Medical Systems	Penfine® Insulin Injection Pen Needle	**29G x 6mm** **30G x 6mm** **31G x 6mm** **29G x 10mm** **30G x 10mm** **31G x 10mm** **29G x 12mm** **30G x 12mm** **31G x 12 mm**

The reference devices are provided for purposes of sizes and lengths that are not available with the predicate devices. The reference devices have same or similar IFUs as the subject device.

Non-Clinical Performance Data: [(807.92(b)(1)]

Verification/Validation testing was done according to the requirements of ISO 11608-2:2012 as summarized below. All testing met the applicable requirements.

Test Parameter	Requirement – ISO 11608-2:2012	Result
Materials	The needle shall be made of tubing materials specified in ISO 9626.	Meets standard
Dimensions	The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.	Meets standard
Determination of flow rate through the needle	The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	Meets standard
Bond between hub and needle tube	The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Meets standard
Freedom from defects	The needle tube shall fulfill the requirements of ISO 7864, 11.3.	Meets standard
Lubrication	The needle tube should be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or	Meets standard

Test Parameter	Requirement – ISO 11608-2:2012	Result
	corrected-to-normal vision, be visible as droplets of fluid on the outside surface of the needle tube.	
Dislocation of measuring point at patient end	Dislocation of the cannula point at the patient end shall be in accordance with Table 2 below when tested as per Clause 8 (of ISO 11608-2).	Meets standard
Determination of functional compatibility with needle-based injection systems	Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11.	Meets standard
Ease of assembly and disassembly	Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.	Meets standard
Pre-conditioning of needles	All requirements of the standard related to preconditioning of needles were met.	Meets standard

Biocompatibility testing

The following biocompatibility testing has been conducted on the Droplet® Pen Needles.
The selection of biocompatibility tests was made based on the requirements of ISO 10993-1.
All the tests have been successfully passed.

Test	Result
Cytotoxicity	Passed
Sensitization	Passed
Intracutaneous Reactivity	Passed
Haemocompatibility	Passed
System toxicity (acute)	Passed
Subchronic toxicity (subacute toxicity)	Passed

Sterility testing

Droplet® Pen Needles are sterilized with Gamma radiation. To ensure sterility of the device over its shelf life, relevant sterility testing is conducted. Droplet® Pen Needles have passed all relevant sterility tests successfully.

Clinical Performance Data: [(807.92(b)(2)]
Clinical data were not provided.

Conclusion: [(807.92(b)(3)]

Droplet® Pen Needles are substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate devices and do not raise any new questions of safety and effectiveness.